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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/065,672	04/23/1998	PATRICIA A. BILLING-MEDEL	6086.US.P1	7811

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EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/065,672

Applicant(s)

BILLING-MEDEL ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-68 is/are pending in the application.
- 4a) Of the above claim(s) 54-56, 60, 61, 64, 65, 67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-59, 62, 63 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 54-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Detailed Action

1. Claims 54-68 are pending.

Election/Restrictions

2. Applicant's election of Group I, claims 57-59, 62-63 and 66 to the extent of SEQ ID NO:5, residues 1-276 in Paper No. 24 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 54-56, 60-61, 64-65 and 67-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 24.

Claim Objections

4. Claims 57-59, 62-63 and 66 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

"Since the decisions in *In re Weber* **, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Hamish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

Instant claims set forth instant SEQ ID NO's which do not share common structure and common utility.

Priority

5. Applicant's claim to priority under 35 USC 120 to patent application 08/838,968 filed 4-23-1997 is acknowledged. However, instant claims 57-59, 62-63 and 66 do not obtain the benefit of the priority date as the '968 application does not provide support for 100% identity of SEQ ID Nos:5, residues 1-276 as instantly claimed, see also Figure 1. The priority document is thus non-enabling with respect to 35 USC 112 for instantly claimed invention. Therefore the effective filing date of instant claims 57-59, 62-63 and 66 is the instant filing dated of 4-23-98.

Specification

6. The disclosure is objected to because of the following informalities: The specification throughout references sequence identifiers as "SEQUENCE ID NO X". However, MPEP 2422 (d) designates that the required reference be "SEQ ID NO:X".

Appropriate correction is required.

Rejections

Claim Rejections - 35 USC § 101 and 112

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 57-59, 62-63 and 66 are rejected under 35 U.S.C. 101, because the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility.

The specification contemplates the use of the disclosed nucleic acids for the identification of markers as indicative of a prostate tissue disease or condition, see in particular p. 11, lines 16-17. The specification further discloses that the isolated nucleic acids of the invention are specific to a PS128 polynucleotide and that the nucleic acids may be used to detect the PS128 sequence in a test sample, see in particular p. 4, lines 10-11. Yet the specification discloses that PS128 is expressed in tissues other than prostate and in normal prostate as well as in prostate cancer tissue, see in particular Figures 3-4. In addition, the claims recite homologous sequences which may not specifically detect the designated PS128 sequence, but alternatively would detect related sequences. Thus the designated utility does not appear to be either specific and substantial because the sequences detect sequences from tissues other than prostate cancer and for prostate regardless of disease or condition. Thus, the use for the nucleic acids appears to merely rely on the inherent properties of any nucleic acid to hybridize to complementary sequences. Therefore, the disclosed nucleic acids merely constitute research reagents for further experimentation to discover the "real-world" use or significance of expression. The examiner further notes that the specification fails to disclose a PS128 gene, open reading frame, polypeptide or epitope for which the nucleic acid fragments are specific. For these reasons there does not appear to be

either a specific and substantial, asserted utility or a well-established utility for the claimed nucleic acids.

Applicant's previously filed arguments (6-5-01) were noted but were not persuasive. In particular the examiner noted that the evidence of detection in both diseased, non-diseased and alternative tissues fails to indicate any particular condition, diagnosis, treatment or cell tissue type and thus it is unclear to the examiner how the instant sequences can be considered diagnostic. In addition, there is no evidence of over expression in any particular diseased state, condition, or evidence that such polynucleotides can be used as a prognostic indicator in particular as no levels of such over expression appear to be indicated. Thus for the aforementioned reasons and a lack of evidence of such asserted utilities the rejection is maintained as previously set forth.

In the amendment of 4-17-02 applicant's submit a declaration under 37 CFR 1.132 describing experimental procedures performed in PS128 prostate cancer (CaP) tissue and benign prostatic hyperplasia (BPH) tissue and assert that the description is of a quantitative analysis demonstrating higher levels of expression in CaP definitively showing that PS128 is useful as a marker to identify CaP.

Applicants declaration and arguments filed 4-17-02 under 37 CFR 1.132 have been fully considered but are not persuasive. The declaration describes RT-PCR analysis performed using the procedures as denoted in point 3 of the declaration. RNA was isolated, amplified via RT-PCR and quantities of PS128 bands obtained on electrophoresis were measured by pixel intensity as described. The results indicated that the amplified product exhibited higher pixel intensity in CaP vs BPH samples. However, the declaration does not speak to the relevance of the amplification procedure to any of the disclosed PS128 sequences in particular or to the elected sequence of

SEQ ID NO:5, residues 1-276. Thus, it is not clear that expression of this region of the PS128 gene was measured via RT-PCR. Further, the skilled artisan readily recognizes the difference between quantitative and non-quantitative RT-PCR. For example, as Freeman et al., *Biotechniques*, (1999 Jan) 26(1):112-125 teaches, successful quantitation involves correction for experimental variations in individual RT and PCR efficiencies, see in particular Abstract. As noted in Figure 1, quantitative RT-PCR requires an RNA standard to assess such variances. While applicants disclose that their methodology uses RT-PCR the declaration does not evidence any procedural methods, controls or standards which would indicate that the reactions were in fact quantitative. Thus, the declaration provides insufficient evidence for the conclusion that the subject matter of instant claims, in particular SEQ ID NO:5 residues 1-276 were overexpressed in CaP or would be useful in discerning CaP tissue from BPH tissue. Therefore the rejection is maintained absent particular evidence of the relevancy of the amplified material in the assay to the noted sequences claimed, in particular SEQ ID NO:5, residues 1-276 and evidence that the procedures used were in fact quantitative as asserted in applicants arguments and not non-quantitative as indicated by the procedural evidence as set forth in the declaration.

10. Claims 57-59, 62-63 and 66 also are rejected under 35 U.S.C. 112, first paragraph as set forth above. Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In addition to the aforementioned deficiencies noted with respect to enablement, the following enablement rejection applies to the claims even in the case where specific and substantial utility is found.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

In particular the claims recite "degenerate codon equivalents thereof". Degenerate codons exist amongst DNA molecules because for a single amino acid there is more than a single nucleic acid triplet encoding it, see in particular Alberts, The Molecular Biology of the Cell, Garland Publishing, 1989, inside front cover, The Genetic Code, Amino acids and their symbols. Thus for any particular amino acid sequence, there are numerous DNA molecules which are capable of encoding it. However, nucleic acid degeneracy is only recognized with respect to a particular amino acid sequence. Instant claims only designate polynucleotides in the absence of any relative reference to an amino acid sequence. There is no specified reading frame as set forth for the SEQ ID NO. Without reference to a relevant amino acid sequence the artisan cannot discern the amino acids to be encoded or the relevant nucleic acids that are degenerates of it. Thus, the skilled artisan cannot make and use the invention as claimed without further undue experimentation.

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11. Claims 57-59, 62-63 and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants claims recite the nucleic acid sequence of residues 1-276 of SEQ ID NO:5. Applicants point to support for the recitation at p. 4, lines 1-4, p. 6, lines 1-3, p. 11, lines 32-35 and p. 12, lines 1-2. However, the specification at such citations does not support the sequence of SEQ ID NO:5, residues 1-276 as claimed. Thus, such recitations constitute new matter absent evidence for support in the specification as originally filed.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 57-59, 62-63 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While the skilled artisan recognized a degenerate codon sequence for any particular amino acid sequence, based on the genetic code, one does not readily recognize a nucleic acid degenerate absent reference to a relevant amino acid sequence it is intended to encode. Thus, the skilled artisan cannot readily discern the nucleotide sequences intended to be encompassed by "degenerate codon equivalents" as recited in the claims.

Status of Claims

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14. No claims are allowed.

Conclusion

15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
11/5/02


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